

WHAT IS CLAIMED IS:

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1. A non-liposomal pharmaceutical formulation comprising:  
at least one pharmaceutically active agent;  
at least one phospholipid; and  
an enteric coating material surrounding said pharmaceutically active agent  
and said phospholipid.
2. The formulation of Claim 1, wherein said pharmaceutically active agent is  
a poorly water soluble drug.
- 10 3. The formulation of Claim 1, wherein said pharmaceutically active agent is  
selected from the group consisting of griseofulvin, famotidine, meclizine, cyclosporine,  
carbamazepine, methotrexate, itraconazole, dipyridamole, mercaptopurine, halofantrine,  
amiodarone, lomustine, testosterone, misoprostil, etoposide, rifamycin, azathioprine,  
glyburide, tolbutamide, aminoglutethimide, taxol, clofibrate, nifedipine, methyldopa,  
ramipril and dicumarol.
- 15 4. The formulation of Claim 1, wherein said phospholipid is a phosphatidyl-  
phospholipid.
- 20 5. The formulation of Claim 1, wherein said phospholipid is selected from  
the group consisting of distearoyl phosphatidylcholine, dipalmitoyl phosphatidylcholine,  
dimyristoyl phosphatidylcholine, egg PC, soy PC, DMPG, DMPA, DPPG, DPPA, DSPG,  
DSPA, phosphatidylserine and sphingomyelin.
- 25 6. The formulation of Claim 1, wherein said enteric coating material is  
selected from the group consisting of cellulose acetate phthalate, alginates, alkali-soluble  
acrylic resins, hydroxypropyl methylcellulose phthalate, methacrylate-methacrylic acid  
copolymers, polyvinyl acetate phthalate and styrol maleic acid copolymers.
7. The formulation of Claim 1, wherein said pharmaceutically active agent is  
selected from the group consisting of anorexics, analgesics, antiarthritics, adrenergic  
blocking agents, steroids, vaccines, peptides, proteins, hormones, antibodies, antibiotics,  
antiviral agents, vitamins, nucleotides, nutritional agents, enzymes, genes, genetic  
material, cytotoxins, bacteria, microbes and viral agents.

8. The formulation of Claim 1, wherein said formulation is in a form selected from the group consisting of capsules, suspensions and liquids.

9. The formulation of Claim 1, wherein said formulation is in tablet form.

5 10. The formulation of Claim 1, further comprising at least one additional ingredient which is pharmaceutically inactive.

11. The formulation of Claim 10, wherein said at least one additional ingredient is selected from the group consisting of carriers, diluents and lubricants.

10 12. The formulation of Claim 10, wherein said at least one additional ingredient is selected from the group consisting of microcrystalline cellulose, starch, lactose, talc, mannitol, polyethylene glycol, polyvinylpyrrolidone, hydroxypropylmethyl cellulose, ethyl cellulose, fatty acids, fatty acid salts, glyceryl behenate, dextrose and dicalcium phosphate.

13. A method for making a non-liposomal pharmaceutical formulation comprising:

15 combining a pharmaceutically active agent with a phospholipid to produce a combination;

coating said combination with an enteric coating material to produce a coated product; and

forming said coated product into a capsule, liquid or suspension.

20 14. The method of Claim 13, wherein said pharmaceutically active agent is a poorly water soluble drug.

25 15. The method of Claim 13, wherein said pharmaceutically active agent is selected from the group consisting of griseofulvin, famotidine, meclizine, cyclosporine, carbamazepine, methotrexate, itraconazole, dipyridamole, mercaptopurine, halofantrine, amiodarone, lomustine, testosterone, misoprostil, etoposide, rifamycin, azathioprine, glyburide, tolbutamide, aminoglutethimide, taxol, clofibrate, nifedipine, methyl dopa, ramipril and dicumarol.

16. The method of Claim 13, wherein said phospholipid is a phosphatidyl phospholipid.

17. The method of Claim 13, wherein said phospholipid is selected from the group consisting of distearoyl phosphatidylcholine, dipalmitoyl phosphatidylcholine, dimyristoyl phosphatidylcholine, egg PC, soy PC, DMPG, DMPA, DPPG, DPPA, DSPG, DSPA, phosphatidylserine and sphigomyelin.

18. The method of Claim 13, wherein said enteric coating material is selected from the group consisting of cellulose acetate phthalate, alginates, alkali-soluble acrylic resins, hydroxypropyl methylcellulose phthalate, methacrylate-methacrylic acid copolymers, polyvinyl acetate phthalate and styrol maleic acid copolymers.

19. The method of Claim 13, wherein said coating comprises spraying said combination with said enteric coating material.

20. The method of Claim 13, further comprising combining at least one additional ingredient which is pharmaceutically inactive with said pharmaceutically active agent.

21. The method of Claim 20, wherein said at least one additional ingredient is selected from the group consisting of carriers, diluents and lubricants.

22. The method of Claim 20, wherein said at least one additional ingredient is selected from the group consisting of microcrystalline cellulose, starch, lactose, talc, mannitol, polyethylene glycol, polyvinylpyrrolidone, hydroxypropylmethyl cellulose, ethyl cellulose, fatty acids, fatty acid salts, glyceryl behenate, dextrose and dicalcium phosphate.

23. The method of Claim 13, wherein said pharmaceutically active agent is selected from the group consisting of anorexics, analgesics, antiarthritics, adrenergic blocking agents, steroids, vaccines, peptides, proteins, hormones, antibodies, antibiotics, antiviral agents, vitamins, nucleotides, nutritional agents, enzymes, genes, genetic material, cytotoxins, bacteria, microbes and viral agents.

24. A method of making a non-liposomal pharmaceutical formulation comprising:

combining at least one pharmaceutically active agent with at least one phospholipid in a non-aqueous solvent;

evaporating said non-aqueous solvent; and

applying an enteric coating material to said pharmaceutically active agent and said phospholipid.

25. The method of Claim 24, wherein said pharmaceutically active agent is a poorly water soluble drug.

26. The method of Claim 24, wherein said pharmaceutically active agent is selected from the group consisting of griseofulvin, famotidine, meclizine, cyclosporine, carbamazepine, methotrexate, itraconazole, dipyridamole, mercaptopurine, halofantrine, amiodarone, lomustine, testosterone, misoprostil, etoposide, rifamycin, azathioprine, glyburide, tolbutamide, aminoglutethimide, taxol, clofibrate, nifedipine, methyldopa, ramipril and dicumarol.

27. The method of Claim 24, wherein said phospholipid is a phosphatidyl phospholipid.

28. The method of Claim 24, wherein said phospholipid is selected from the group consisting of distearoyl phosphatidylcholine, dipalmitoyl phosphatidylcholine, dimyristoyl phosphatidylcholine, egg PC, soy PC, DMPG, DMPA, DPPG, DPPA, DSPG, DSPA, phosphatidylserine and sphigomyelin.

29. The method of Claim 24, wherein said enteric coating material is selected from the group consisting of cellulose acetate phthalate, alginates, alkali-soluble acrylic resins, hydroxypropyl methylcellulose phthalate, methacrylate-methacrylic acid copolymers, polyvinyl acetate phthalate and styrol maleic acid copolymers.

30. The method of Claim 24, wherein said applying an enteric coating material comprises spraying said pharmaceutically active agent and said phospholipid with said enteric coating material.

31. The method of Claim 24, further comprising combining at least one additional ingredient which is pharmaceutically inactive with said pharmaceutically active agent.

32. The method of Claim 31, wherein said at least one additional ingredient is selected from the group consisting of carriers, diluents and lubricants.

33. The method of Claim 31, wherein said at least one additional ingredient is selected from the group consisting of microcrystalline cellulose, starch, lactose, talc,

mannitol, polyethylene glycol, polyvinylpyrrolidone, hydroxypropylmethyl cellulose, ethyl cellulose, fatty acids, fatty acid salts, glyceryl behenate, dextrose and dicalcium phosphate.

5 34. The method of Claim 24, wherein said pharmaceutically active agent is selected from the group consisting of anorexics, analgesics, antiarthritics, adrenergic blocking agents, steroids, vaccines, peptides, proteins, hormones, antibodies, antibiotics, antiviral agents, vitamins, nucleotides, nutritional agents, enzymes, genes, genetic material, cytotoxins, bacteria, microbes and viral agents.

10 35. The method of Claim 24, wherein said formulation is in a form selected from the group consisting of capsules, suspensions and liquids.

36. The method of Claim 24, wherein said formulation is in tablet form.

37. A method for delivering the pharmaceutical formulation of Claim 1 to a mammal comprising orally administering said pharmaceutical formulation to said mammal.

15 38. A method for diagnosing, preventing or treating an illness in a mammal comprising administering the pharmaceutical formulation of Claim 1, wherein said pharmaceutical agent is provided in a biologically active dose.

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